Message

From: Faeth, Lisa [Faeth.Lisa@epa.gov]
Sent: 6/4/2019 2:42:36 PM
To: Anderson, Steve [Anderson.Steve@epa.gov]; Askinazi, Valerie [Askinazi.Valerie@epa.gov]; Baptist, Erik [Baptist.Erik@epa.gov]; Barkas, Jessica [barkas.jessica@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Blair, Susanna [Blair.Susanna@epa.gov]; Buster, Pamela [Buster.Pamela@epa.gov]; Canavan, Sheila [Canavan.Sheila@epa.gov]; Caraballo, Mario [Caraballo.Mario@epa.gov]; Carroll, Megan [Carroll.Megan@epa.gov]; Cherepy, Andrea [Cherepy.Andrea@epa.gov]; Christian, Myrta [Christian.Myrta@epa.gov]; Corado, Ana [Corado.Ana@epa.gov]; Davies, Clive [Davies.Clive@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]; Devito, Steve [Devito.Steve@epa.gov]; Doa, Maria [Doa.Maria@epa.gov]; Drewes, Scott [Drewes.Scott@epa.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]; Dunton, Cheryl [Dunton.Cheryl@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Edmonds, Marc [Edmonds.Marc@epa.gov]; Elwood, Holly [Elwood.Holly@epa.gov]; Fan, Shirley [Fan.Shirley@epa.gov]; Farquharson, Chenise [Farquharson.Chenise@epa.gov]; Fehrenbacher, Cathy [Fehrenbacher.Cathy@epa.gov]; Feustel, Ingrid [feustel.ingrid@epa.gov]; Frank, Donald [Frank.Donald@epa.gov]; Gibson, Hugh [Gibson.Hugh@epa.gov]; Gimlin, Peter [Gimlin.Peter@epa.gov]; Gorder, Chris [Gorder.Chris@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Grant, Brian [Grant.Brian@epa.gov]; Gray, Shawna [Gray.Shawna@epa.gov]; Groeneveld, Thomas [Groeneveld.Thomas@epa.gov]; Guthrie, Christina [Guthrie.Christina@epa.gov]; Hanley, Mary [Hanley.Mary@epa.gov]; Helfgott, Daniel [Helfgott.Daniel@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Kapust, Edna [Kapust.Edna@epa.gov]; Kemme, Sara [kemme.sara@epa.gov]; Koch, Erin [Koch.Erin@epa.gov]; Krasnic, Toni [krasnic.toni@epa.gov]; Lavoie, Emma [Lavoie.Emma@epa.gov]; Lee, Mari [Lee.Mari@epa.gov]; Lee, Virginia [Lee.Virginia@epa.gov]; Leopard, Matthew (OEI) [Leopard.Matthew@epa.gov]; Liva, Aakruti [Liva.Aakruti@epa.gov]; Lobar, Bryan [Lobar.Bryan@epa.gov]; Menasche, Claudia [Menasche.Claudia@epa.gov]; Morris, Jeff [Morris.Jeff@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]; Mottley, Tanya [Mottley.Tanya@epa.gov]; Moyer, Adam [moyer.adam@epa.gov]; Myers, Irina [Myers.Irina@epa.gov]; Myrick, Pamela [Myrick.Pamela@epa.gov]; Nazef, Laura [Nazef.Laura@epa.gov]; Ortiz, Julia [Ortiz.Julia@epa.gov]; Owen, Elise [Owen.Elise@epa.gov]; Parsons, Doug [Parsons.Douglas@epa.gov]; Passe, Loraine [Passe.Loraine@epa.gov]; Pierce, Alison [Pierce.Alison@epa.gov]; Pratt, Johnk [Pratt.Johnk@epa.gov]; Price, Michelle [Price.Michelle@epa.gov]; Reese, Recie [Reese.Recie@epa.gov]; Reisman, Larry [Reisman.Larry@epa.gov]; Rice, Cody [Rice.Cody@epa.gov]; Richardson, Vickie [Richardson.Vickie@epa.gov]; Ross, Philip [Ross.Philip@epa.gov]; Sadowsky, Don [Sadowsky.Don@epa.gov]; Santacroce, Jeffrey [Santacroce.Jeffrey@epa.gov]; Saxton, Dion [Saxton.Dion@epa.gov]; Scarano, Louis [Scarano.Louis@epa.gov]; Scheifele, Hans [Scheifele.Hans@epa.gov]; Schmit, Ryan [schmit.ryan@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]; Scott Selken [spselken@up.com]; Scott, Elizabeth [Scott.Elizabeth@epa.gov]; Selby-Mohamadu, Yvette [Selby-Mohamadu.Yvette@epa.gov]; Seltzer, Mark [Seltzer.Mark@epa.gov]; Sheehan, Eileen [Sheehan.Eileen@epa.gov]; Sherlock, Scott [Sherlock.Scott@epa.gov]; Simons, Andrew [Simons.Andrew@epa.gov]; Sirmons, Chandler [Sirmons.Chandler@epa.gov]; Slotnick, Sue [Slotnick.Sue@epa.gov]; Smith, David G. [Smith.DavidG@epa.gov]; Smith-Seam, Rhoda [smith-seam.rhoda@epa.gov]; Stedeford, Todd [Stedeford.Todd@epa.gov]; Stevens, Katherine [stevens.katherine@epa.gov]; Strauss, Linda [Strauss.Linda@epa.gov]; Symmes, Brian [Symmes.Brian@epa.gov]; Tanner, Barbara [Tanner.Barbara@epa.gov]; Thompson, Tony [Thompson.Tony@epa.gov]; Tierney, Meghan [Tierney.Meghan@epa.gov]; Tillman, Thomas [Tillman.Thomas@epa.gov]; Tomassoni, Guy [Tomassoni.Guy@epa.gov]; Tran, Chi [Tran.Chi@epa.gov]; Turk, David [Turk.David@epa.gov]; Vendinello, Lynn [Vendinello.Lynn@epa.gov]; Wallace, Ryan [Wallace.Ryan@epa.gov]; Wheeler, Cindy [Wheeler.Cindy@epa.gov]; Widawsky, David [Widawsky.David@epa.gov]; Williams, Aresia [Williams.Aresia@epa.gov]; Williams, Bridget [Williams.Bridget@epa.gov]; Williamson, Tracy [Williamson.Tracy@epa.gov]; Wills, Jennifer [Wills.Jennifer@epa.gov]; Wise, Louise [Wise.Louise@epa.gov]; Wolf, Joel [Wolf.Joel@epa.gov]; Wright, Tracy [Wright.Tracy@epa.gov]; Yowell, John [yowell.john@epa.gov]
Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Coffee Won't Need Cancer Warning in California After All (1)

By Edvard Pettersson

Posted June 4, 2019, 9:22 AM

California coffee lovers can indulge their caffeine habit without worry now that the state has decided the beverage doesn't need a cancer warning after all.

EPA Rule Keeping Scientists Off Boards Challenged in Court Again

By Porter Wells

Posted June 3, 2019, 3:53 PM

An EPA policy that keeps agency grantees off of scientific advisory boards is again being challenged in court.

FDA Getting Mixed Results on Nonstick Chemicals in Food (1)

By David Schultz

Posted June 3, 2019, 10:45 AMUpdated June 3, 2019, 3:25 PM

Scientists with the FDA are examining different food items to see their content of a potentially toxic nonstick chemical, according to information the agency plans to release next week.

INSIDEEPA.COM ARTICLES

Citing Unintended Effects, Industry Sues Over EPA's Methylene Chloride Ban

A chemical industry trade association is suing EPA over its first-time Toxic Substances Control Act (TSCA) ban on consumer uses of paint-strippers containing methylene chloride, charging the measure goes too far by unintentionally limiting access to some commercial uses even though it does not intend to.

Asbestos Group Cites OSHA In Seeking Strict TSCA Risk Evaluation

The Asbestos Disease Awareness Group (ADAO) is urging EPA to perform a strict assessment of asbestos' human health risk, citing in part findings by the Occupational Safety and Health Administration (OSHA) and others that there is no safe level of exposure to the toxic mineral as some fear EPA will soften its analysis.

OIG Touts $295 Million Savings For EPA But Sees No Environmental Gains

EPA's Office of Inspector General (OIG) says that at the halfway point of fiscal year 2019 it has more than tripled its target for annual "return on investment" by producing $295 million in cost savings, monetary benefits and additional fines for the agency, but achieved no environmental improvements or regulatory changes in the same period.

California Lawmakers Advance Toxics Division Overhaul, Fee Reform Plan

California lawmakers are advancing a restructuring and fee reform budget proposal for the state's embattled Department of Toxic Substances Control (DTSC), while limiting Gov. Gavin Newsom's (D) proposed General Fund backfill budget for the agency to only the coming fiscal year instead of the next three.

GREENWIRE ARTICLES

States take up PFAS fight: 'Is this the next asbestos?'

Ellen M. Gilmer and Ariana Figueroa, E&E News reporters Published: Monday, June 3, 2019

A firefighter sprays firefighting foam at a training facility. Peter Muller/Newscom

State lawyers are lining up in court to fight PFAS, the vexing group of chemicals linked to cancer but used broadly in cookware, firefighting foam and other materials.

Litigation has increased as research and public awareness of potential impacts of per- and polyfluoroalkyl substances has grown in recent years. Now, state lawsuits against chemical manufacturers are piling up, raising the stakes for all involved.

https://www.eenews.net/greenwire/2019/06/03/stories/1060469135

Nature Conservancy president resigns on sexual misdeed probe

Jeremy P. Jacobs, E&E News reporter Published: Monday, June 3, 2019

Brian McPeek is pictured here in an undated file photo. The Nature Conservancy

The Nature Conservancy announced Friday that its president, Brian McPeek, was resigning after an investigation into sexual harassment allegations.

McPeek was one of three executives at the global advocacy group who were the subjects of an internal probe into misconduct.

The other two, Vice Presidents Mark Burget and Kacky Andrews, left the Nature Conservancy last week after the investigation concluded they did not properly disclose their romantic relationship — an allegation they deny.

"On May 31, Brian McPeek, president of The Nature Conservancy, and Mark Tercek, CEO, jointly agreed that the best way for TNC to move forward at this time is for Brian to resign," a spokesperson for the Arlington, Va.-based group said in an email this morning confirming Friday's announcement to staff.

https://www.eenews.net/greenwire/2019/06/03/stories/1060469625

FDA food sampling finds PFAS contamination in meat, cake

Published: Monday, June 3, 2019

The Food and Drug Administration's first broad testing of food for a worrisome class of nonstick, stain-resistant industrial compounds found substantial levels in some grocery store meats and seafood and in off-the-shelf chocolate cake, according to unreleased findings FDA researchers presented at a scientific conference in Europe.

The FDA's disclosure is likely to add to concerns raised by states and public health groups that the Trump administration is not acting fast enough or firmly enough to start regulating the man-made compounds, nicknamed "forever chemicals" (*see related story*). A federal toxicology report last year cited consistent associations between very high levels of the

industrial compounds in people's blood and health risks but said there was not enough evidence to prove the compounds as the cause.

The levels in nearly half the meat and fish tested were double or more the only currently existing federal advisory level for any kind of the widely used compounds, which are called per- and polyfluoroalkyl substances, or PFAS.

https://www.eenews.net/greenwire/2019/06/03/stories/1060468727

Industry opposes pending ban on plastic shopping bags

Published: Monday, June 3, 2019

Vermont is poised to implement what advocates call one of the most comprehensive bans in the country on single-use plastic bags and other measures designed to reduce plastic pollution, but the industry is calling on Gov. Phil Scott (R) to veto the measure.

The bill, passed overwhelmingly by the Legislature, takes aim at the thin bags handed out at grocery stores, straws, and polystyrene food containers.

Scott has said he is inclined to sign the legislation but has not yet made up his mind.

Matt Seaholm, of the American Progressive Bag Alliance, which represents U.S. plastic bag manufacturers, tells Vermont Public Radio more energy is used to produce replacement paper or cloth bags. And the reusable heavy-duty plastic bags that the Vermont bill allows are made in China and take more energy to produce and ship.

https://www.eenews.net/greenwire/2019/06/03/stories/1060468325

CHEMICAL WATCH ARTICLES

REACH & CLP Hub: SVHC authorisation – review report or new report?

3 June 2019 / Europe, REACH, SVHCs

Frederik Johanson of REACHLaw examines company strategies for successful REACH authorisation applications.

REACH authorisation is required for SVHCs included in Annex XIV of REACH (the authorisation list).

This means that companies need to apply for authorisation to continue their relevant uses after the sunset date. Applicants for authorisation can either be the users, commonly referred to as a downstream user application, or the manufacturers and/or importers supplying the Annex XIV listed substance to the users, commonly referred to as an upstream application.

An application may also be a combination of the two (eg, formulators who supply their formulation for further use downstream). Applications for authorisations may be submitted by a single company (single application for authorisation) or by a group of companies (joint application for authorisation).

To benefit from so-called transitional arrangements, the authorisation application must be submitted before the latest application date given in the authorisation list entry.

Transitional arrangements mean that the applicant(s) as well as their downstream users, where relevant, can continue their use after the sunset date, also given in the authorisation list entry, if their decision is not yet available from the European Commission.

After the sunset date, only companies that benefit from transitional arrangement or have an authorisation in force can continue their use. All others must stop their use effective from the sunset date.

Where an authorisation application is accepted by the Commission, the use covered will be subject to a time-limited review period. At the end of this period, the authorisation holder(s) must submit a review report or cease or substitute the use of the substance. The length of the review period granted is based on several factors, such as the availability of alternatives, the level of certainty that the operating conditions and risk management measures in place for the use minimise exposure and socio-economic arguments such as a long investment cycle.

'Four years is considered a short review period, seven years is considered a standard review period and 12 years is considered a long review period'

Four years is considered a short review period, seven years is considered a standard review period and 12 years is considered a long review period. The length of the review period is ultimately determined by the Commission taking into consideration the Opinions of the Committee for Risk Assessment (Rac) and the Committee for Socio-economic Analysis (Seac). The Commission may also reject an application for authorisation, resulting in a ban on the use of the substance by the applicant(s) from the sunset date.

Initial application for authorisation

By 22 May, 142 applications for authorisation had been received by Echa, covering 227 uses by 235 applicants. The Commission has given 203 decisions per use and per applicant. These have been initial applications for authorisation, meaning these have been submitted for the first time for that substance-use-combination.

Review report

If an authorisation holder has not found a suitable alternative during his granted review period, the holder can submit a review report to continue use. A review report is basically a re-application for authorisation and includes updates to all the documents submitted with the original application (Chemical Safety Report (CSR), Analysis of Alternatives (AoA) and the Socio-Economic Assessment (SEA) if applicable) an explanatory note describing what has changed as well as any other information that may have been required by the conditions of use given in the Commission decision.

 In order to benefit from transitional arrangements, this review report must be submitted at least 18 months before the end of the review period, and the authorisation holder can continue their use even if the Commission has not given its decision on their review report by the end of the review period. There is no limit to the number of times a review report can be submitted. Essentially, as long as the prerequisites for authorisation are fulfilled (ie, on the socio-economic route if there are no suitable alternatives and the socio-economic benefits outweigh the risk to human health or the environment) one can re-apply for authorisation "forever", according to REACH.

As of 22 May, only three review reports have been submitted covering five uses by three applicants. Of these, one applicant has withdrawn the review reports for both uses.

What is a successful application for authorisation?

From the applicant's perspective, the success of an application for authorisation is determined solely by the length of the review period granted unless it was a bridging application to cover residual time until an alternative can be implemented.

Generally, a review period of seven years is considered a good outcome, while 12 years is considered an excellent outcome providing continuity of use for a substantial period until a decision is taken whether to substitute or phase out the use or submit a review report. Four years or less is considered a poor outcome.

'An important factor for determining success should be the severity or harshness of the given conditions of use as part of the authorisation decision'

However, an important factor for determining success should be the severity or harshness of the given conditions of use as part of the authorisation decision. Harsh monitoring and reporting requirements, especially for upstream applications for complex supply chains, may yield practical problems at the downstream user level in implementing these conditions of use and at the upstream level, in collecting potential monitoring data that has been reported by the downstream users to Echa.

Albeit the final decision is not yet published, based on draft decisions, this seems to be happening for some of the chromium trioxide uses where downstream users would have 12 months from the date of the decision to collect a number of exposure measurements, per supplier, and report it directly to Echa, who in turn will share the information with the upstream authorisation holder to enable them to verify and validate their exposure scenarios.

Therefore, the success of an application for authorisation may be measured as a combination of the length of the review period and the degree of stringency of possible conditions of use imposed on the applicant and the users of the substance.

New, initial application for authorisation or review report

As the first authorisation applications were submitted in 2013 and the first authorisation decisions were published in 2014, it is becoming more relevant for authorisation holders to either discontinue or substitute their use, or re-apply for an authorisation by submitting a review report at the latest 18 months before the end of the review period.

As part of the strategy for re-applying, several factors come into play depending on the type of authorisation. For single downstream users, the options are limited, either:

- re-apply; or
- substitute/phase-out the use by the end of the review period.

For those that are part of a joint downstream application, the options are not much better, either:

- re-apply;
- substitute/phase-out the use by the end of the review period; or
- submit initial applications for authorisation as a single downstream user, focusing on the single downstream user-specific information in the hopes of having a stronger case resulting in longer review periods and lesser stringent conditions of use by avoiding uncertainties in the assessment reports.

However, in cases where an upstream authorisation holder has covered the downstream uses of the substance, there are more options available for the downstream users. This article will now focus on upstream authorisation holders and their review reports or subsequent new, initial, applications for authorisation.

Upstream authorisation holders

In situations where the upstream holder is considering renewing the existing authorisation by submitting a review report, downstream users essentially have the option of:

- being covered by the upstream review report, assuming the upstream actor wishes to continue coverage of the use; or
- submitting their own downstream user initial application for authorisation.

This can further be done as a single downstream user or group of downstream users as part of a joint application for authorisation.

Therefore, from the downstream users' perspective, the benefits and drawbacks of submitting a new, initial downstream user application for authorisation need to be considered.

Pros and Cons

When determining the benefits and drawbacks of submitting an own (single/joint) application for authorisation it is also worth looking beyond the mere technical aspects of the application to other potential strategic risks, such as political and reputational risks.

 For example, some NGOs have taken an interest in certain rather weak and wide-ranging upstream applications for authorisation, exerting pressure on the decision-making process in favour of short review periods or even not granting the authorisation at all.

Therefore, the unfortunate negative press or stigma attached to an upstream application may also be a reason enough to submit the company's own (single/joint) application for authorisation to break the "vicious" circle by starting from a clean slate.

Therefore, the following pros and cons can be identified for new, initial applications of authorisation instead of relying on the upstream review report, taking into account technical, business as well as reputational aspects.

The pros of submitting a new, initial application instead of relying on the upstream review report include (note that some of the pros also generally apply to downstream user applications for authorisation) include:

- gain independence from the upstream authorisation holder supplier(s). The company is no longer subject to their authorisation but can, for example, source the substances from any supplier inside and outside of the EU/EEA, provided the substance complies with the other requirements of REACH such as the registration requirement, where applicable;
- only cover the use(s) relevant for the company. – Obtain focus with the application by covering only the relevant use(s) applicable to the company
- The company is not bound by review report conditions of use. – There are no previous conditions of use for the company's new, initial application for authorisation albeit, where applicable, the company will have to comply with the conditions of use of the application for authorisation until the Commission decision has been given on the new application;
- less stringent conditions of use are likely given to more specific applications. Downstream user applications for authorisation tend to be more specific and thus more robust. Looking horizontally across applications submitted to date, downstream user applications have better outcomes as the information submitted will generally be more case specific and relevant for the use which is favoured by both the Rac and Seac;
- no association with "stigmatised" upstream applications for authorisation, where applicable and avoid the reputational risks associated with those applications. Even if the upstream applicant submits a better review report, it is likely the association with the previous application will remain, at least to some degree;
- applicants can be changed. As part of the review reports, the applicant must be one of the named current applicants of the upstream application for authorisation;

- adopt a strategy to group substances, where applicable/relevant. The substance scope of the review report cannot change whilst for new, initial applications for authorisation, the scope is to be determined by the downstream user(s); and/or

- freedom to redefine use description (broader/different beyond scope). The use scope of the review report cannot go beyond the original application while for new, initial applications for authorisation, the use scope is as to be defined by the downstream user(s).

Cons of submitting a new, initial application instead of relying on the upstream review report include:

- transitional arrangements do not apply. The biggest drawback by far is that no transitional arrangements apply for initial application for authorisation as they do for review reports that are submitted at least 18 months before the end of the review period; and

- costs. The cost of applying for authorisation, especially in small groups or submitting individually, will likely be higher than relying on the upstream application for authorisation. The costs originate from the development of the authorisation dossier as well as the Echa fees, however, these can be mitigated if submitting a joint application for authorisation whereby all the applicants share the costs.

Transitional arrangements only apply to review reports and not to the initial applications for authorisation. Therefore, transitional arrangements reduce the risk of having to cease the use waiting for the decision of the initial application for authorisation.

'Downstream users should seriously consider applying for authorisation for their own uses, either individually or by forming groups'

However, recognising the drawbacks and mitigating the related effects by sharing costs and submitting initial applications for authorisations in good time, at least 24 months before the end of the review period of the upstream application, it could be argued that the benefits of an initial application outweigh the drawbacks. Therefore, downstream users should seriously consider applying for authorisation for their own uses, either individually or by forming groups for the purpose of a joint application for authorisation.

Brexit considerations

One additional twist to determining a sound strategy – whether to rely on a review report or to submit an own new, initial application for authorisation – is Brexit and its implications.

The next key Brexit date is 31 October, when the UK is scheduled to leave, and there is still no certainty on what kind of exit deal will be agreed.

If companies are a UK downstream user, currently relying on an upstream authorisation where the authorisation holder is located in the EU-27/EEA, the company will be covered until the end of the review period of that application.

However, it is still not entirely clear what will happen after that review period ends and whether the company will be covered by the (potential) upstream EU-27/EEA review report or not.

Furthermore, even if a downstream user will be (or can be) legally covered in the UK by an EU-27/EEA review report in the future, the upstream applicant must take UK socio-economic aspects into consideration in the review report. If not, it is likely that UK downstream users would not be covered by such review reports. Therefore, UK downstream users should consider submitting a new, initial, downstream user application for authorisation to mitigate risks and gain control over their use of the substance.

Therefore, the list of pros given above should also include the following (for UK downstream users):

- in case of Brexit as a UK downstream user, companies should get coverage by an own authorisation post-Brexit, allowing the continued use of the substance in the UK after the review period of the EU-27/EEA application for authorisation is over.

The final outcome of Brexit will, of course, determine whether UK-REACH applications for authorisation need to be submitted or not and much of the practical details of UK-REACH authorisations are still not available and may change closer to the new Brexit deadline.

Conclusion

For those who require use of an SVHC to be covered by an authorisation, having an authorisation in place is usually a business-critical issue.

Taking into account the available information, in the case of being dependent on the re-application of the upstream applicant, the recommendation is to seriously consider applying for authorisation as a downstream user, either as a single or joint applicant, by analysing the benefits versus the drawbacks of such actions.

The views in this article are those of the expert author and are not necessarily shared by Chemical Watch.

Frederik Johanson

Partner, sales REACHLaw

Related Articles

- Austria defends Echa's Seac following NGO criticism
- REACH & CLP Hub: After the final registration
- Brexit: REACH registration transfers exceed 5,000
- SVHC use fee could improve substitution under REACH, expert says

Further Information:

- Echa: Statistics on received applications for authorisation and review reports

Expert Focus: Chemours' NOV indicates EPA may be expanding TSCA enforcement

4 June 2019 / PFCs, TSCA, United States, US states

Stephen E O'Day, head of the environmental law and sustainability practices at US firm Smith, Gambrell & Russell, and associate Vickie C Rusek consider the opportunity for increased enforcement in light of Chemours' NOV.

In the realm of US EPA enforcement actions, TSCA is often overshadowed by other statutes such as the Clean Air Act, Clean Water Act, and the Comprehensive Environmental Response, Compensation, and Liability Act.

While it is true that total enforcement numbers under TSCA are dwarfed by enforcement actions under these other environmental statutes, there may be reason to expect an uptick—particularly with regard to per- and polyfluoroalkyl substances (PFASs), which have been the target of recent social and political concern.

The EPA recently cited Chemours, a spin-off from DuPont, for alleged violations of TSCA related to Chemours' manufacture of PFASs, among other chemicals. In the Notice of Violation (NOV) issued to Chemours, the EPA alleges that Chemours failed to submit a Pre-Manufacture Notice (PMN) in violation of TSCA Section 5, failed to comply with a TSCA Significant New Use Rule (Snur) requiring it to submit a Significant New Use Notice (Snun) for GenX compounds (a form of PFAS) to be manufactured in an enclosed process, and failed to submit a Snun for hexafluoropropylene oxide (HFPO), which is manufactured as part of the manufacture of other PFASs.

The NOV also alleges that Chemours failed to control effluent and emissions during the use of GenX as required by a TSCA consent order (EPA, Consent Order and Determinations Supporting Consent Order for PMN Substances P-08-508 and P-08-509 [2009]) and failed to comply with the Chemical Data Reporting (CDR) Rule under TSCA Section 8. The EPA required Chemours to take immediate action to correct the violations, and noted that its investigation remained ongoing.

'Stepping up' enforcement

Although enforcement authority has been available to the EPA under TSCA since 1976, enforcement actions have been infrequent in recent years compared to other environmental statutes.

The Chemours' NOV may be an indication of the EPA's intent to step up enforcement under TSCA, particularly for PFASs. On 14 February, the day after it issued the Chemours' NOV, the EPA published a PFAS Action Plan under which it outlined the steps the agency is taking to address PFASs.

In it, the EPA says one such action is to use legal tools such as TSCA to prevent future PFAS contamination. It notes that more than 1,000 PFASs are included on the TSCA Inventory List, of which approximately half are known to be commercially active within the last decade.

 The Action Plan also notes that the EPA is considering public comments received on 2015 proposed Snurs and the new statutory requirements of the Act to issue a supplemental proposed Snur on PFASs, specifically related to the manufacture and import of certain long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances.

On 25 April, the EPA published a draft set of recommendations for cleaning up groundwater contaminated with PFOA and PFOS for public comment as part of its PFAS Action Plan.

PFAS legislation continues to be a hot topic, with members of Congress having introduced more than 20 bills this session addressing PFASs in some capacity.

These developments may suggest that stepped up enforcement under TSCA is aimed solely at the regulation of PFASs.

'Companies subject to TSCA should pay close attention to TSCA's myriad requirements, and protect themselves and their operations against potential enforcement actions'

Because they also may suggest broader enforcement under TSCA, companies subject to TSCA should pay close attention to TSCA's myriad requirements, and protect themselves and their operations against potential enforcement actions.

The EPA's authority under TSCA

TSCA provides the EPA with the authority to require certain notices, reports, recordkeeping, and testing and to impose restrictions and conditions on the commercial manufacture, import, use, and/or disposal of certain chemical substances and/or mixtures.

TSCA Section 5(a) requires anyone who plans to manufacture or import into the US a new chemical substance for a commercial purpose to notify the EPA before initiating the activity with a PMN.

TSCA Section 5(a) also empowers the EPA to issue a Snur, which will then require the submission of Snun to the EPA at least 90 days before they manufacture, import, or process the chemical substance that is the subject of the Snur. The EPA must then assess any risk that may be associated with the significant new use.

One common outcome of the EPA's review of a PMN or Snun is the issuance of an order under TSCA Section 5(e), which contains conditions for the manufacture, use, and/or processing of the chemical subject to the Snur.

Such orders usually take the form of a Consent Order, consented to by the EPA and the submitter. The CDR Rule, issued under TSCA Section 8, requires manufacturers and importers of certain chemicals in commerce to provide information

about the chemicals and their uses to the EPA once every four years, when production volumes meet or exceed 25,000 pounds for a specific reporting year.

The EPA has the authority to enforce TSCA through civil penalties, criminal actions, and/or injunctive relief.

TSCA Section 16(a) authorises the EPA to impose civil penalties of up to $37,500 (£29,700) per violation, per day, after an opportunity for a hearing. Under TSCA Section 16(b), the EPA is authorised to seek criminal penalties of up to $50,000 per day per violation, imprisonment for one year, or both upon any person who knowingly and willingly violates TSCA.

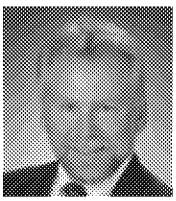
The EPA is also authorised to seek appropriate action in the US district courts to restrain any person from violating TSCA, or compel any action required by TSCA.

TSCA changes

TSCA, originally enacted in 1976, was fundamentally overhauled under the 2016 Lautenberg amendments. Among the notable changes are the following:

- Section 6 replaces the "least burdensome requirement" with a risk-based safety standard and requires a timeline for completion of prioritisation, risk evaluation, and control actions. Expedited action is required for persistent, bioaccumulative, and toxic chemicals (PBTs);
- Section 4 expands the EPA's authority to require testing on the health and environmental effects of TSCA chemicals through an administrative order;
- The new Section 14 requires substantiation of certain Confidential Business Information (CBI) claims; and
- Section 18 leaves in place existing state chemical control laws enacted before 31 August 2003 and other state measures taken before 22 April 2016. It introduces "pause" preemption, whereby new state actions are preempted during the EPA's risk evaluation of a chemical substance, with the preemption ending after 30 months or whenever the EPA completes its risk evaluation and determines that the unreasonable risk posed by the chemical no longer exists. If the EPA determines that a chemical in particular uses does not pose an unreasonable risk, states are preempted from regulating those uses of the chemicals.

Note: Your access to this subscriber-only article is through a corporate subscription



Stephen E. O'Day

View transparency statement

Related Articles

- New Hampshire sues PFAS, firefighting foam manufacturers
- Chemours faces first Notice of Violation issued under TSCA
- Precise GenX mechanism of toxicity eludes EPA scientists

- US EPA announces PFAS action plan
- Members of US Congress launch PFAS action taskforce

Further Information:

- Chemours NOV
- Inspection report

Maine legislature advances workplace chemicals resolution

4 June 2019 / Occupational hygiene, US states

The US stated of Maine's legislature has voted in favour of a resolution addressing the use of hazardous chemicals in the workplace.

If adopted into law, the measure (LD 1017) would direct the state's Department of Labor to develop a framework for identifying hazardous chemicals in the workplace and determine safer alternatives. Collaboration with "interested parties", as well as employers and employees in industries that often use concerning substances, would be part of this process.

The legislation further directs the department to submit a report of its findings to the legislature by 20 December. This could inform a bill on hazardous chemicals in a future legislative session.

The bill cleared the House on 28 May and the Senate a day later. It will be sent to governor Janet Mills for consideration.

Further Information:

- LD 1017

Industry discusses 'tension' in alternatives assessment outlook

Community must move towards standardisation despite need to retain flexibility

4 June 2019 / Alternatives assessment & substitution, Global, Risk assessment

There is a "tension" between providing a universally applicable standardised framework for alternatives analysis and retaining sufficient flexibility to accommodate all decision contexts, according to an expert. However, the community must go in the direction of standardisation, she said.

Molly Jacobs, senior research associate at the University of Massachusetts, Lowell, was responding to a comment at the Society of Environmental Toxicology and Chemistry (Setac) conference in Helsinki on 28 May.

During a panel discussion, Julian Hunter, director of sustainable value at AkzoNobel, said that the number of alternatives analysis frameworks available – over 20 and growing – was too high to work with.

"This notion of consistency and alignment – it's a conversation that's happening," Ms Jacobs replied. However the field should not "go so far as to be so prescriptive that you disrupt this principle of flexibility, given the various decision contexts in which this framework would be used".

Joel Tickner, professor of public health at the University of Massachusetts, added that there was no one framework for risk assessment.

"You've got some best practices out there but different governments do it different ways. So don't expect more out of alternatives assessment than you expect out of risk assessment. They use a lot of the same inputs and trying to get perfection often can be the enemy of good."

Ms Jacobs said that the available frameworks were aligned across "the general process and the general steps" and that the variation between them was in the emphasis placed on certain elements.

The framework published by the US National Research Council in 2014, entitled *A framework to guide selection of chemical alternatives,* has gone a long way towards standardising approaches in North America, she added.

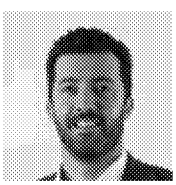
Transparency

Asked whether there was also a tension between the need for transparency about alternatives and the need for protection of confidential business information, Ms Jacobs said that the latter need not be a limitation.

Anna Lennquist, senior toxicologist at NGO ChemSec, added that transparency has increased considerably in recent years and companies now feel much more comfortable sharing information. Ten years ago, for example, they would not have shared restricted substance lists, she said.

The A4

Ms Jacobs and Professor Tickner are part of a US group of researchers and practitioners who last year established the Association for the Advancement of Alternatives Assessment (A4). The president of the association is currently Pam Spencer, senior director of regulatory and product stewardship at the Angus Chemical Company.



Andrew Turley

Science editor, Chemical Watch

Related Articles

- Alternatives assessment: the need for a robust framework
- Alternatives assessment gathers steam with launch of dedicated organisation

Further Information:

- NRC framework on alternatives assessment

Illinois passes bills on receipts with BPA, cosmetics animal testing

Legislature also sends ethylene oxide measures to governor

4 June 2019 / Alternative approaches to testing, Bisphenols, Personal care, Retail, US states

State lawmakers in Illinois have passed measures to ban receipts containing bisphenol A (BPA) and the sale of cosmetics tested on animals. The bills (HB 2076 and SB 241) will now be delivered to Governor JB Pritzker for consideration.

Initially filed by Representative Karina Villa (D), HB 2076 calls for amending the state's Environmental Protection Act to prohibit the manufacture of paper that contains BPA in the coating, and to bar the distribution or use of such thermal paper for making receipts and other business and banking records.

If adopted as law, the ban would take effect from 1 January 2020. Thermal paper manufactured prior to that date would be exempted.

The bill initially passed 76-37 in the House of Representatives on 11 April, but was significantly amended when it reached the Senate. The new version received unanimous approval in the Senate on 21 May and in the House on 30 May.

Illinois governor Jay Pritzker will have 60 days to either sign or object to the bill, or it will become law without his signature.

Connecticut became the first US state to ban BPA thermal paper receipts in 2011. New York and Massachusetts have introduced legislation this year to enact bans of their own, although neither measure (S 1096 and S 1247, respectively) has advanced out of committee.

Meanwhile, California's Assembly is considering legislation to block businesses from providing a paper receipt unless requested, due in part to the risk that BPA exposure poses to retail workers. Illinois' 2019 legislative session also saw the introduction of a similar 'skip the slip' measure (HB 3486), but it has stalled in committee.

Cosmetics animal testing

In a separate action, Illinois' legislature has agreed a measure to block manufacturers from importing or selling cosmetics that have been tested on animals.

Like a measure that became law in California last year, the bill includes certain exemptions for products that are tested to satisfy requirements from other jurisdictions. And it does not apply to products or ingredients tested before the legislation takes effect.

If signed into law, the prohibition will come into force from 1 January 2020, with a 180-day sell through period of existing inventory.

Ethylene oxide emissions

Legislators in Illinois also sent to the governor two bills addressing ethylene oxide (EtO) – a substance used in medical sterilisation practices that was discovered to be present in the environment in the state.

The first (SB 1852) addresses capture and emissions from EtO sterilisation operations, while the second (SB 1854) deals with fugitive emissions from those businesses.

Both measures passed the legislature on 30 May.

Kelly Franklin and Lisa Martine Jenkins

Related Articles

- Connecticut becomes first US state to ban BPA thermal paper receipts
- California legislature moves forward chemicals in products bills
- California cosmetics animal testing bill becomes law
- US Congress round-up

Further Information:

- HB 2076
- HB 3486
- SB 241
- SB 1852
- SB 1854

© 2019. Reprinted and distributed by kind permission of Chemical Watch.

OTHER ARTICLES

Coleen Healy: Enact S.37 for the protection of my children

vtdigger.org

... paid for by polluters because of the toxic chemicals in their body. This bill would reassure parents of their kids' health and give them peace of mind, ...

How chemicals are affecting human health

The New Times

The blood brain barrier (protecting brain from microbes and **harmful chemicals**) is also affected, resulting in serious infections affecting the brain like ...

Dangers of food and water in plastics

The Nation Newspaper

Leaching, in this context, is the release of **harmful chemicals** from plastics or cellophane (nylon) bags into the contents it carries, be it food or liquid ...